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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,178	08/21/2001	Brian J. Brown	S63.2N-5605-US05	8077
490 7590 08/10/2009 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344				
EXAMINER				
PREBILIC, PAUL B				
ART UNIT		PAPER NUMBER		
3774				
MAIL DATE		DELIVERY MODE		
08/10/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

09/934,178

## Applicant(s)

BROWN ET AL.

## Examiner

Paul B. Prebille

## Art Unit

3774

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9, 10, 13-22 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 10, 13-22 and 24-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

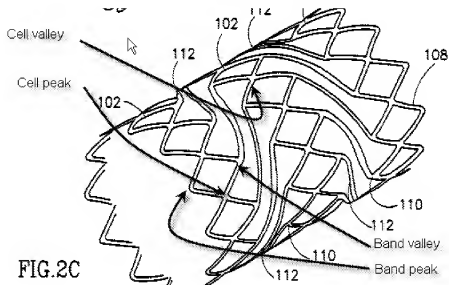
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17, 20, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Pinchasik et al (US 5,449,373).

Pinchasik meets the claim language where the peaks of adjacent ends of the cell are clearly offset; see Figures 2A to 2C. Each cell has two cross supports between a cell peak or valley and a band peak or valley. There are serpentine band peaks and valleys and there are cell peaks and valleys; see the figure below.



In an alternative interpretation, it is noted that "cell" has no special definition. The only example given is that of the specification insertion made to page 4 stating that "[i]nterconnecting elements 20 and adjacent segment 16 form a plurality of cells 24 that change shape upon expansion of the stent." However, openings in stents are called by numerous terms within the art such as cells, openings apertures, holes, etc. For this reason, since cells are only exemplified as bounded by interconnecting elements, Pinchasik meets the claim language in the openings in the segments (102) are not bounded by interconnecting elements so they are not cells.

With regard to claim 20, the shorter bands as claimed are those bands between adjacent diamonds of adjacent serpentine bands; see Figure 2C.

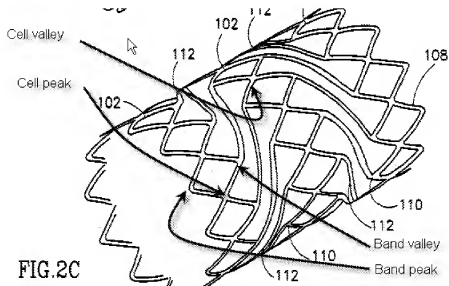
Claims 17, 20, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated over Palmaz et al (US 5,102,417). Palmaz meets the claim language where the annular elements as claimed are met by the prostheses or grafts (70) of Palmaz and the connectors as claimed are the connectors (100) or spiral members (102) of Palmaz; see Figures 7 to 10 and column 11, line 35 et seq. The cell peaks and valleys are different from the band peaks and valleys as explained in the Pinchasik rejection *supra*. The same rationale used in the interpretation of Pinchasik rejection is utilized herein.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 25-26 and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchasik et al (US 5,449,373) in view of Kleshinski (US 5,902,317). Pinchasik meets the claim language where the peaks of adjacent ends of the cell are clearly offset; see Figures 2A to 2C. There are serpentine band peaks and valleys and there are cell peaks and valleys; see the figure below.



But Pinchasik fails to disclose a "structure" that provides the stent with less compression resistance than provided by the structure of a different annular element. However, Kleshinski teaches that it was known to put fingers on end cells in order to make them less compression resistant than other cells; see Figures 1 to 4 and column 4, lines 3-20. Therefore, it is the Examiner's position that it would have been obvious to put fingers on the ends of the segments for the same reasons that Kleshinski does the same.

Claims 16, 25-26, and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (US 5,102,417) in view of Kleshinski (US 5,902,317). Palmaz meets the claim language where the annular elements as claimed are met by the prostheses or grafts (70) of Palmaz and the connectors as claimed are the connectors (100) or spiral members (102) of Palmaz; see Figures 7 to 10 and column 11, line 35 et seq. However, Palmaz fails to disclose a "structure" that provides the stent with less compression resistance than provided by the structure of a different annular element. However, Kleshinski teaches that it was known to put fingers on end cells in order to make them less compression resistant than other cells; see Figures 1 to 4 and column 4, lines 3-20. Therefore, it is the Examiner's position that it would have been obvious to put fingers on the ends of the segments of Palmaz for the same reasons that Kleshinski does the same.

Claims 9, 10, 13-15, 21, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israel (US 5,733,303) in view of Pinchasik (US 5,449,372) and Kleshinski (US 5,902,317). Israel discloses a flexible expandable stent that has annular elements called meander patterns (11) and (12) and connecting members called loops (18) and (20); see Figures 1 to 4 and column 2, line 45 to column 3, line 62. Although the stent can be bent to match the curvature of the blood vessel (see Figure 3), it is not clear that the first end can be circumferentially offset from the second end. Furthermore, although the end annular elements would be less crush resistance than the middle annular elements due to greater connector support, it is not clear that "the

structure" of the end annular elements would have less compression resistance than the middle elements.

Pinchasik teaches that circumferentially offset connectors were known where similar meander pattern stents were made and as an alternative to circumferentially aligned cell ends; see Figure 2C and compare it to Figure 3C. Therefore, it is the Examiner's position that it would have been obvious to circumferentially offset the cell ends of Israel for the same reasons that Pinchasik does the same or in order to provide better coverage between stent segments.

Kleshinski teaches that it was known to have end elements with less compression resistance by putting fingers on end cells in order to make them less compression resistant than other cells; see Figures 1 to 4 and column 4, lines 3-20. The fingers have the same shape as the valley portions when the stent is compressed; see Figure 5 of Kleshinski. Furthermore, Kleshinski also teaches that it was known to lengthen cells as a means to reduce crush resistance where the cells have the same general shape; see column 4, lines 21-40 of Kleshinski. Therefore, it is the Examiner's position that it would have been considered *prima facie* obvious to an ordinary artisan to extend or elongate the end segments of Israel for the same reasons that Kleshinski does the same, that is, the reduce the radial bias at the ends of the stent.

Regarding claims 14 and 15, Israel discloses making the stents out of metal (see column 4, lines 26-31) but not of Nitinol or shape memory materials as claimed. However, Kleshinski teaches that it was known to make similar stents out of shape memory materials such as Nitinol; see column 4, lines 49-67. Therefore, it is the

Examiner's position that it would have been obvious to make the stents of Israel out of Nitinol or shape memory material for the same reasons that Kleshinski teaches substituting the same.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz (US 5,102,417) or Pinchasik et al (US 5,449,373) as applied against claim 17 above, and further in view of Lau et al (US 5,514,154). Palmaz or Pinchasik discloses making the stents out of various materials but not of Nitinol or shape memory materials as claimed. However, Lau teaches that it was known to make similar stents out of Nitinol (Nitinol is a NiTi alloy with shape memory properties) or shape memory material as an alternative to balloon expandable stents; see column 2, lines 12-56 and the paragraph bridging columns 6 and 7. Therefore, it is the Examiner's position that it would have been obvious to make the stents of Palmaz or Pinchasik out of Nitinol or shape memory material for the same reasons that Lau teaches substituting the same.

### ***Response to Arguments***

Applicant's arguments filed May 26, 2009 have been fully considered but they were not considered persuasive.

In response to the argument that each cell must have connectors to define them, the Examiner previously modified the rejection statement to address this argument. In particular, there is nothing in the claim language that precludes the cells from having cross supports. Furthermore, since the meaning of "cell" has no special definition and has only been used in an exemplary fashion, it can be given its broadest ordinary and reasonable interpretation. The only usage of "cell" is provided by the specification



insertion made to page 4 stating that "[i]nterconnecting elements 20 and adjacent segment 16 form a plurality of cells 24 that change shape upon expansion of the stent."

**It should be noted that the present disclosure did not even contain the term "cell" until it was added to the specification on May 28, 2003, that is, about 2 years after the present application was filed and about 8 years after the parent application was filed.** Openings in stents are called by numerous terms within the art such as cells, openings, apertures, holes, etc. For this reason, since cells are only exemplified as bounded by interconnecting elements, Pinchasik meets the claim language in the openings in the segments (102) are not bounded by interconnecting elements so they are not cells.

Furthermore, giving the claim language the narrower interpretation that cross supports are precluded within cells, the Examiner has again applied the rejection utilizing Israel, Pinchasik, and Kleshinski. Since the claimed features distinguishing Israel from the claimed invention were known to the art at the time the invention was made, the Examiner asserts that the claimed invention would have been considered clearly *prima facie* obvious to an ordinary artisan.

With regard to the traversal of the rejections utilizing Israel, the examiner previously added further explanations as to how the claim language is being interpreted. For example, the fingers have the same shape as the valley portions when the stent is compressed; see Figure 5 of Kleshinski. Furthermore, Kleshinski also teaches that it was known to lengthen cells as a means to reduce crush resistance where the cells have the same general shape; see column 4, lines 21-40 of Kleshinski. Therefore, it is

the Examiner reasons that it would have been considered *prima facie* obvious to extend or elongate the end segments of Israel for the same reasons that Kleshinski does the same, that is, the reduce the radial bias at the ends of the stent.

The Applicant also argues that Israel teaches away from the combination because Israel states helical connectors of another reference is "most probably harmful to the blood vessel"; see page 11 of the May 26, 2009 response. However, this statement of Israel is clearly speculative, and it is directed to a reference that is not utilized in the rejection that has a markedly different structure. For these reasons, the statement of Israel is considered insufficient evidence that Israel teaches away from the proposed combination; see MPEP 2123 that is incorporated herein by reference.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilio whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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